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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,352	07/25/2003	Vladimir Knezevic	6457-65777	2321

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EXAMINER
YU, MELANIE J

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 09/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

Office Action Summary	Application No.	Applicant(s)	
	10/627,352	KNEZEVIC ET AL.	
	Examiner	Art Unit	
	Melanie Yu	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 July 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *47-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *47-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 July 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *14062005* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment and arguments filed 1 July 2005 has been entered. Claims 1-46 are canceled. Claims 47-52 are new and currently pending in this application.

Withdrawn Rejections

2. Rejections of claims 22-26, 28, 32-38 and 44-46 have been withdrawn in light of Applicant's new limitations presented in new claims 47-52.

Claim Rejections - 35 USC § 112

3. Claims 47-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear whether the targeted biomolecule is claimed as part of the kit recited in claim 47. The claim recites captor molecules capable of capturing a targeting molecule and a biomolecule-permeable support, but do not specifically recite targeted biomolecules as part of the kit. Furthermore, it is unclear whether the targeted biomolecules are the same as a targeted molecule in line 10 of claim 47 or if a separate targeted molecule is capable of capture with a captor molecule.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 47-49 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Woodrum et al. (US 4,959,305) in view of Greenquist et al. (US 4,668,619) and Ciechanover et al. (US 5,384,255).

Woodrum et al. teach a kit comprising: a stack of membranes separable from one another (carrier member with multiple layers encompasses a stack of layers that are formed separately and are therefore separable, col. 14, lines 46-61), each membrane comprising a biomolecule-permeable (migration of analyte indicates biomolecule-permeation, col. 16, lines 53-65; col. 9, lines 34-37) having a porous substrate (col. 3, line 55-col. 4, line 12) which permits transfer of targeted biomolecules therethrough (col. 16, lines 53-65); one or more of the substrates being treated with a captor molecule capable of capturing a targeted molecule (binding partner, col. 16, lines 56-63); and detectors (labels, col. 16, lines 53-55). Although Woodrum et al. does not specifically teach the use of the kit or membranes separable after a capturing step is completed, such limitations are drawn to intended uses of the product and do not appear to provide any further structural limitations to the kit of the instant invention, and therefore the kit of Woodrum et al. is capable of use in the recited method and for separating membranes after completion of a capturing step. However, Woodrum et al. fail to teach a specific pore size, a membrane thickness of less than 30 microns and containers comprising detectors.

Greenquist et al. teach a kit comprising: a stack of membranes separable from one another (carrier member with multiple layers encompasses a stack of layers that are formed separately and are therefore separable, col. 12, lines 5-11; col. 13, line 65-col. 14, line 7), each membrane comprising a biomolecule-permeable (impregnation of reagents indicates that layers are biopermeable, col. 11, lines 16-28), polycarbonate substrate (col. 12, lines 42-44) having a thickness 5-100 microns (col. 12, lines 50-54) which encompasses the recited less than about 30 microns, in order to permit transfer of targeted biomolecules therethrough (col. 11, lines 16-28).

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the kit of Woodrum et al., polycarbonate substrates with a thickness of between 5 and 100 microns as taught by Greenquist et al., in order to provide increased permeability.

Ciechanover et al. teach containers comprising probe detectors, which are labeled antibodies (col. 19, lines 34-45), applied to a test strip (col. 16, lines 44-58) after target molecules are captured (col. 18, line 50-col. 19, line 26), in order to provide a simple yes/no assay for determination of the presence of an antigen.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the kit of Woodrum in view of Greenquist et al., containers comprising antibody detectors which are applied to the membranes after targeted biomolecules are captured as taught by Ciechanover et al., in order to perform a sandwich specific binding assay and provide close confinement storage for detector antibodies in a kit, which provide increased convenience and efficiency.

Woodrum et al. fail to teach a specific pore size of between about 0.1 to 5.0 microns. However it has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value for a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation" Application of Aller, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation." Id. at 458, 105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill

of the art." Since applicant has not disclosed that the specific limitations recited in instant claim 47 are for any particular purpose or solve any stated problem, and the prior art teaches that the pore size may be varied in order to permit analyte to permeate, absent unexpected results, it would have been obvious for one of ordinary skill to discover the optimum workable ranges of the methods disclosed by the prior art by normal optimization procedures know in the porous membrane art.

Regarding claim 52, Woodrum et al. teaches 4 layers of porous material (col. 20, lines 22-40), but fail to specifically recite a stack comprising 5-10 membranes. However, it has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value for a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation" Application of Aller, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation." Id. at 458, 105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Since applicant has not disclosed that the specific limitations recited in instant claim 52 are for any particular purpose or solve any stated problem, and the prior art teaches that the number of layers (membranes) can be varied in order to enhance and/or modulate the performance of a multilayer device, absent unexpected results, it would have been obvious for one of ordinary skill to discover the optimum workable ranges of the methods disclosed by the prior art by normal optimization procedures know in the multilayer assay art.

5. Claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over Woodrum et al. (US 4,959,305) in view of Greenquist et al. (US 4,668,619) and Ciechanover et al. (US 5,384,255), as applied to claim 47, and further in view of Pipas et al. (US 6,168,929).

Woodrum et al. in view of Greenquist et al. and Ciechanover et al., as applied to claim 47, teach a kit comprising containers comprising antibody detectors, but fail to teach a cocktail of antibodies.

Pipas et al. teach an antibody cocktail, in order to probe analytes blotted onto membranes (col. 17, lines 5-11).

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the kit of Woodrum et al. in view of Greenquist et al. and Ciechanover et al., a detector comprising a cocktail of antibodies as taught by Pipas et al., in order to probe multiple target analyte.

Response to Arguments

6. Applicant's arguments with respect to claims 47-52 have been considered but are moot in view of the new ground(s) of rejection. In view of applicant's amendment the rejection of claims 1-46 have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of applicant's new limitation requiring a biomolecule-permeable substrate.

Conclusion

7. No claims are allowed.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Yu whose telephone number is (571) 272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Melanie Yu
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09/15/05